

Remarks:

The Subject Application presently includes claims 1, 2, 4-8, 10, 12-20, 32-34, and 53. Of these pending claims, claim 1 is the single independent claim.

Applicants and the undersigned wish to thank the Examiner for his consideration of Applicants' August 24 and September 20, 2007 responses and accompanying declarations, and for withdrawing several of the previous bases for rejecting and objecting to the Subject Application's claims. In particular, in the Office Action the Examiner states that Applicants' previous responses have resulted in withdrawal of: (i) the previous rejections of claims 1-2, 4-8, 10, 12, 16-20, and 32-34 under 35 U.S.C. § 112, first paragraph; (ii) the previous rejections of claims 13-14 under 35 U.S.C. § 103(a) over Smith (US 3,356,542) in view of Thielemann (US 3,241,954); (iii) the previous rejection of claim 15 under § 103(a) over Smith in view of Crook (US 4,353,742); and (iv) the previous objection to claim 14.

In the Office Action, the Examiner has maintained his earlier rejections of claims 1, 2, 4-8, 10, 12, 16-20, and 32-34 under § 103(a) as having been obvious over Smith. Regarding independent claim 1, in the Office Action the Examiner refers to the grounds for this rejection set forth in the February 27, 2007 Office Action. There, the Examiner asserted that the alloy composition described in Smith "overlaps with the composition of the claimed invention." The Examiner further asserted that a prima facie case of obviousness exists because "[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to select the claimed compositions of an alloy from the composition disclosed by Smith ... because Smith ... discloses the same utility (alloy wire) throughout the disclosed ranges."

Regarding the limitations Applicants added to claim 1 in the August 24 response that the alloy includes "at least one of at least 0.05 to 0.15 weight percent aluminum, at least 5 to 20 ppm calcium, at least 5 to 50 ppm magnesium, and at least 5 to 50 ppm cerium", as well as "no greater than 0.035 weight percent carbon", the Examiner argues that Smith discloses adding 0 to 2 weight percent aluminum and no more than 0.05

weight percent of carbon, boron, oxygen, nitrogen, or beryllium to the alloy.

Applicants continue to traverse the Examiner's assertion that the claims under examination would have been obvious to one having ordinary skill considering Smith. As was discussed exhaustively and supported by uncontradicted declaratory evidence in Applicants' August 24 and September 20, 2007 responses, Smith does not teach or suggest all of the elements and limitations of claim 1. Therefore, the Examiner has not established a *prima facie* case that the claimed subject matter would have been obvious. Also, as Applicants previously established, secondary considerations, including unexpected results, commercial success, and long-felt need, clearly show that the claimed inventions would not have been obvious. Applicants address each of these points in detail below.

1. No Prima Facie Case

The Examiner has not established a *prima facie* case of obviousness based on Smith because Smith neither teaches nor suggests all of the elements and limitations of at least claim 1 of the Subject Application. Claim 1 of the Subject Application is directed to an alloy including, among other things, "less than 30 ppm nitrogen". However, Smith only briefly refers to nitrogen in the following sentence appearing at col. 4, lines 68-72: "It is critically important that the alloy composition contain no more than 0.05% of carbon, boron, oxygen, nitrogen, or beryllium, the total of these components being no more than 0.1%."

Applicants note that 0.05 weight percent is equal to 500 ppm, which exceeds the less than 30 ppm nitrogen claim limitation by more than 16 times. Even if it can be said that a statement in Smith that the Smith alloy contains no more than 500 ppm nitrogen includes the complete absence (0%) of nitrogen (which we do not concede), that statement is not sufficiently specific to teach or suggest the limitation "less than 30 ppm nitrogen", a limitation which the inventors have discovered is critical to the performance of the claimed alloy. See MPEP 2131.03 ("If the claims are directed to a narrow range, [and] the reference teaches a broad range, ... [i]t may be reasonable to conclude that

the narrow range is not disclosed with 'sufficient specificity' to constitute an anticipation of the claims." (citing *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999 (Fed. Cir. 2006)).

The *Atofina* decision cited in MPEP 2131.03 is particularly pertinent here. In *Atofina* the U.S. Court of Appeals for the Federal Circuit considered whether a prior art reference's teaching of a temperature range of 100 to 500°C effectively disclosed the 330 to 450°C temperature range recited in a claim. The court held that it did not, even though the claimed range was fully encompassed by the prior art range:

Here, the prior art, JP 51-82250, discloses a temperature range of 100 to 500°C which is broader than and fully encompasses the specific temperature range claimed in the '514 patent of 330 to 450°C. Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate this limitation of the claim. Because the court's determination that JP 51-82250 disclosed the temperature range in claims 1, 2, 6, 7, 9, and 10 of the '514 patent was [erroneous], we must reverse its finding of anticipation based on the temperature range.

Atofina, 441 F.3d at 999 (emphasis added). The *Atofina* court went even further – in discussing a second prior art reference that referred to a temperature range of 150 to 350°C, the court held:

[T]he disclosure of a range of 150 to 350°C does not constitute a specific disclosure of the endpoints of that range, i.e., 150°C and 350°C, as Great Lakes asserts. The disclosure is only that of a range, not a specific temperature in that range, and the disclosure of a range is no more a disclosure of the end points of the range than it is of the intermediate points.

441 F.3d at 1000 (emphasis added).

Thus, a prior art reference disclosing a broad range must expressly or implicitly refer to a sub-range with a relatively high degree of specificity to support the rejection of a claim reciting the sub-range. For example, as the appellate holding in *Atofina* demonstrate, it is even the case that a range described in a prior art reference does not necessarily teach the endpoints of the stated range with the requisite "sufficient

specificity".

Echoing the Federal Circuit's restrictive interpretation in *Atofina*, MPEP 2131.03 explains that the question of what constitutes "sufficient specificity" is similar to that of whether a generic teaching "clearly envisages" a species. This is discussed in MPEP 2131.02 as follows:

If one of ordinary skill in the art is able to 'at once envisage' the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be 'at once envisaged.' ...

Clearly, claim 1 of the Subject Application claims a very narrow range (up to 30 ppm) while, at least in relative terms, Smith refers to a very broad range ("no more than" 500 ppm). It is appropriate to adopt here the Federal Circuit's reasoning in *Atofina*: "Given the considerable difference between the claimed range and the range in the prior art, no reasonable fact finder could conclude that the prior art describes the claimed range with sufficient specificity to anticipate..." (see *Atofina, supra*) the up to 30 ppm limitation of claim 1 of the Subject Application. One considering Smith's disclosure of a range of no more than 500 ppm would not "at once envisage" the recited range of less than 30 ppm nitrogen. Moreover, even if we assume for sake of argument that Smith teaches a range of with an upper limit of 500 ppm nitrogen, such a teaching does not mean that Smith teaches a 0 ppm nitrogen endpoint, as the Examiner suggests. Therefore, in keeping with the law as set out in *Atofina* and MPEP 2131.02, Smith does not teach, nor does it suggest, a nitrogen range of less than 30 ppm.¹

Indeed, Applicants established that one having ordinary skill would have considered Smith as teaching an alloy that necessarily included well in excess of 30 ppm nitrogen, despite the statement in Smith that the Smith alloy should include "no

¹ The Examiner appears to rely on MPEP 2144.08(II)(4)(a) for the conclusion that Smith teaches 0 weight percent nitrogen (see the Office Action at page 9, lines 4-6). That MPEP section, however, does not address that issue. In fact, it may be argued that the following passage from that MPEP section supports the opposite position: "There is no absolute correlation between the size of the prior art genus and a conclusion of obviousness. *Id.* Thus, the mere fact that a prior art genus contains a small number of members does not create a *per se* rule of obviousness."

more than 0.05%" nitrogen. Applicants submitted the Declaration of Henry E. Lippard (the "Lippard Declaration") with the August 24, 2007 response. The Lippard Declaration confirms that at the time the Subject Application was filed one having ordinary skill would not have read Smith to teach or suggest limiting nitrogen in the Smith alloy to less than 30 ppm. Specifically, the Lippard Declaration includes the following uncontradicted statements directed to the nitrogen concentration of Smith:

12. I have thoroughly reviewed U.S. Patent No. 3,356,542 issued to Smith ("Smith"). Smith does not describe or suggest an alloy that includes less than 30 ppm of nitrogen. Although Smith does state that the alloy described in that patent should include "no more than 0.05%" nitrogen, that level is more than 15 times the maximum nitrogen level critical to the invention described in the Application. Smith does not describe or suggest that there is any benefit whatsoever to limiting the nitrogen level in the alloy of that patent to less than 30 ppm, or even to very small, ppm range, concentrations.

13. Given that Smith does not state or suggest that the alloy in that patent has or would benefit from having less than 30 ppm nitrogen, or even very low (ppm range) nitrogen levels, the alloy of Smith would certainly have included at least 50 ppm nitrogen. For example, 50 ppm is the minimum level of nitrogen found in conventional MP35N alloy. Although Smith does refer offhand to vacuum melting, such techniques were well known at the time, and Smith does not state or suggest that melting under vacuum should be done for reducing alloy nitrogen levels or otherwise. Smith does not state or suggest any reason why one would have undertaken the involved, time-consuming, and costly steps necessary to limit nitrogen in the alloy described in Smith to less than 30 ppm or to any other extremely low level.

14. Absent limiting nitrogen to these very low levels recited in claim 1, alloy microstructure could not be substantially free of titanium nitride and mixed metal carbonitride inclusions. Also, Smith does not specifically describe or otherwise suggest a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith does not teach or suggest an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

Therefore, in the Lippard Declaration, Dr. Lippard, who is one having at least ordinary skill in the art, attests that Smith does not describe or suggest a nitrogen level of less than 30 ppm. Further, Dr. Lippard explains that the alloy of Smith necessarily

would have included at least 50 ppm nitrogen, which, as discussed in the Subject Application, is the minimum level of nitrogen that was found in a conventional MP35N alloy prior to the present invention and at the time of Smith. Absent some identified motivation to take the extraordinary steps of the present inventors to limit nitrogen in the alloy of claim 1 to extremely low levels, less than 30 ppm, the alloy of Smith would include a significantly greater nitrogen concentration due to, for example, nitrogen in the raw materials and in the furnace atmosphere. Again, Smith does not describe or suggest any reason why one of ordinary skill would take the significant and costly steps to limit nitrogen in the Smith alloy to such extremely low levels of less than 30 ppm. Therefore, the Examiner's reference to the nitrogen range of Smith as "0-0.05" in the Table included in the Office Action does not accurately characterize the teaching of Smith. Absent restricting nitrogen content to less than 30 ppm, as is recited in claim 1, one also could not develop the microstructure that is specifically recited in claim 1.

In the Office Action the Examiner does not refer to the Lippard Declaration. However, the Examiner is required to consider the Lippard Declaration and carefully weigh the uncontroverted statements it includes regarding Smith. MPEP 2145, for example, states that "[c]onsideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments", and that "Office personnel should avoid giving evidence no weight, except in rare circumstances." MPEP 2145 also explains:

Office personnel should consider all rebuttal arguments and evidence presented by applicants. See, e.g., Soni, 54 F.3d at 750, 34 USPQ2d at 1687 (error not to consider evidence presented in the specification). C.f., *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996) (error not to consider factual evidence submitted to counter a 35 U.S.C. 112 rejection); *In re Beattie*, 974 F.2d 1309, 1313, 24 USPQ2d 1040, 1042-43 (Fed. Cir. 1992) (Office personnel should consider declarations from those skilled in the art praising the claimed invention and opining that the art teaches away from the invention.); *Piasecki*, 745 F.2d at 1472, 223 USPQ at 788 ("[R]ebuttal evidence] may relate to any of the Graham factors including the so-called secondary considerations."). ...

[Rebuttal evidence] may also include evidence of the state of the art, the level of skill in the art, and the beliefs of those skilled in the art. See, e.g., *In re Oelrich*, 579 F.2d 86, 91-92, 198 USPQ 210, 214 (CCPA 1978) (Expert opinions regarding the level of skill in the art were probative of the Nonobviousness of the claimed invention.)

Applicants respectfully submit that the Examiner must take into account the Lippard Declaration when assessing what is taught or suggested by Smith. The Lippard Declaration includes uncontested statements of a technical nature, made by one having at least ordinary skill, regarding the state of the art at the time of Smith. As there is no basis in the record to ignore or devalue the statements in the Lippard Declaration, those statements must be accepted at face value. See MPEP 716.02(g) ("The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.")

The Examiner apparently contends that despite (1) Dr. Lippard's uncontested statements of the then-existing state of the art and understanding of ordinarily skilled persons in the art, and (2) the holdings of the Federal Circuit and directives of the MPEP discussed above, Smith nevertheless teaches the recited nitrogen range simply because it states, without elaboration, that the Smith alloy should include "no more than" 500 ppm nitrogen. That determination cannot be maintained and should be reversed.

Therefore, Smith does not disclose, does not suggest, and would not have included an alloy including less than 30 ppm nitrogen. It follows that the Examiner has not established a *prima facie* case that the invention recited in claim 1 of the Subject Application would have been obvious since such a rejection requires that all the claim limitations are taught or suggested by the prior art. MPEP 2143.03.

Absent limiting nitrogen to the very low level of less than 30 ppm in conjunction with certain other recited limitations of the composition, the alloy microstructure would not be substantially free of titanium nitride and mixed metal carbonitride inclusions, as is recited in claim 1. Additionally, Smith does not specifically teach or otherwise suggest a

microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions. Accordingly, Smith also does not disclose, does not suggest, and would not have included an alloy having a microstructure that is substantially free of titanium nitride and mixed metal carbonitride inclusions and that, instead, includes well-tolerated substantially spherical oxide inclusions, as is recited in claim 1.

For at least the foregoing reasons, the rejection based on Smith should be withdrawn

2. Any Established Obviousness Was Rebutted

Even if we assume that the Examiner did establish a *prima facie* case of obviousness based on Smith, Applicants submitted evidence of secondary considerations that rebutted any such case. Specifically, Applicants submitted declarations of Dr. Lippard and Robert Myers showing that the claimed invention: (1) addressed a long-felt and unmet need; (2) provides unexpected results; and (3) has met with substantial commercial success. Applicants address each of these types of evidence below.

a. Long Felt and Unmet Need

As discussed in the August 24, 2007 response and in the Lippard Declaration, the alloy recited in claim 1 of the Subject Application addresses a long-felt and, until the claimed invention was made available, unmet need for an MP35N alloy having substantially improved fatigue resistance that can be formed into small-diameter alloy wire for use in pacemaker leads and other surgical implants. The Examiner did not address this evidence in the Office Action. The Examiner must consider this evidence. See MPEP 2145.

b. Surprising and Unexpected Results

Applicants submitted the Lippard Declaration, providing detailed and uncontradicted evidence of unexpected results, and the Myers Declaration, providing detailed and uncontradicted evidence of commercial success. The Examiner, however,

discounts the pertinence of this uncontradicted evidence for reasons that cannot be sustained, and which Applicants address below.

The Examiner apparently argues that the Lippard Declaration, attesting to unexpected results, is not suitably tied to the subject matter recited in the claims under examination because "the scope of independent claims 1 and 53 are directed to an alloy and not a wire and the scope of the dependent claims do not limit the scope of the alloy to a wire."² (See the Office Action at page 9, lines 8-16.) In other words, the Examiner does not contend that the evidence presented by Applicants fails to show an unexpected and unobvious result, or a result that lacks practical significance. MPEP 716.02(b) ("The evidence relied upon should establish 'that the differences in results are in fact unexpected and unobvious and of both statistical and practical significance.'") Instead, the Examiner apparently concludes that a comparison of the fatigue properties of alloys formed into wires does not establish that properties of the alloys significantly differ. Applicants disagree.

As noted in the August 24, 2007 response, the Subject Application includes unambiguous comparative data showing that small diameter wire formed of the claimed alloy is substantially more fatigue resistant than wire formed from conventional MP35N alloy. Dr. Lippard's declaration also attests to that the improvement in fatigue resistance was unexpected and surprising:

11. As discussed in detail in the Application, an apparent result of the ... fundamentally different microstructure of the small-diameter wire produced from the alloy described in the Application [is that the alloy] exhibits very substantially improved fatigue resistance relative to conventional MP35N alloy. Table 9 of the Application, for example, shows that at 100 ksi, a stress level similar to that to which cardiac pacemaker leads are subjected in service (*i.e.*, implanted in the body), wire formed from the alloy described in the Application withstood at least 797% the number of cycles in rotary beam fatigue testing than wire produced from conventional MP35N alloy, and the modified alloy had a fatigue endurance limit of between 100-110 ksi versus the 90 ksi limit of

² Applicants note that claim 53 is a dependent claim, incorporating the elements and limitations of claim 1.

the conventional alloy. This improvement in fatigue properties was very significant, was surprising to me and my co-inventors, and was not expected even after we observed the fundamentally altered microstructure of the alloy of the Application. ...

The improved fatigue resistance of the claimed alloy is a function of the alloy's composition and microstructure – it is not a result of the process of forming the alloy into a small-diameter wire. If the unexpected fatigue resistance were related to the process of drawing the alloy into wire, then the conventional MP35N wire would have exhibited substantially the same fatigue resistance as the experimental wire. Instead, because the alloy claimed in the Subject Application and the conventional MP35N alloy were formed into wire in the same way and were tested in the same way, effectively canceling out any influence of the wire forming process, it necessarily follows that the improvement in fatigue resistance is attributable to the differences between the alloys.

The essence of a meaningful comparison of properties is that the inventive alloy and the closest prior art alloy were evaluated under identical conditions, which is what occurred here. If, for example, the tensile strength of the conventional and claimed alloys were compared, then an identical tensile test specimen would have been machined from each alloy and tested on the particular tensile testing machine under identical conditions. The alloy, however, would be used commercially to make articles of manufacture (wire, for example) and not tensile test specimens. Nevertheless, would the Patent Office require that the claims under examination recite "a tensile test specimen" consisting of the inventive alloy in order to tie the showing of unexpected results to the claimed invention? Of course the Office would not! Alternatively, if salt water corrosion resistance of the conventional and claimed alloys had been compared to establish unexpected results, then an identical corrosion test specimen (a square coupon, for example) would have been prepared from each alloy, the specimens would have been subjected to an identical salt water solution under identical test conditions, and corrosion performance would have been observed over time. Would the Patent Office require that the claims under examination recite "a corrosion test specimen" consisting of the inventive alloy in order to properly tie the unexpected results to the

claimed invention? Again, of course the Office would not! It is common practice, and is more meaningful to assessing patentability, to evaluate the properties of alloy specimens under real-life conditions when considering whether an unexpected improvement is provided in mechanical properties. Here, it is respectfully submitted that Applicants supplied the perhaps the most meaningful evidence of the alloy's unexpected and surprising properties that could be fashioned – the inventors investigated the long-term fatigue performance of the alloy of the invention relative to that of conventional MP35N alloy (the closest prior art) by drawing the alloys to small-diameter wire form and testing the wire samples under conditions simulating a real-life environment in which the alloys are used.

Therefore, the Examiner's apparent position that the claims must be directed to "a wire" composed of the inventive alloy cannot be sustained. The compelling evidence of unexpected and surprising improvement in fatigue performance clearly relates to the alloy and effectively rebuts any *prima facie* case of obviousness that the Examiner may have established.

In addition, Applicants note that Paragraphs 9 and 10 of the Lippard Declaration explain that the alloy claimed in the Subject Application had an entirely unexpected, surprising, and particularly advantageous microstructure. That microstructure directly addressed certain microstructural deficiencies in conventional MP35N alloy:

9. In an attempt to address the observed microstructural deficiencies in MP35N alloy, we experimented with modifications to the chemistry of conventional MP35N alloy. We surprisingly discovered that modifying the existing alloy chemistry to limit nitrogen to extremely low levels, less than 30 ppm, reducing titanium to less than 0.7 weight percent, and including certain small concentrations of at least one of aluminum, calcium, magnesium, or cerium resulted in an alloy with a fundamentally different microstructure – the microstructure substantially lacked cuboidal titanium nitride and mixed metal carbonitride inclusions and, instead, included relatively small, generally spherical oxide inclusions. We observed that the relatively small, generally rounded oxide inclusions are well tolerated by (i.e., would not heavily score) the wire drawing equipment, substantially reducing the incidence of wire surface defects, and are much less likely to concentrate stresses in the wire to a degree resulting in wire fracture during drawing or when subjected to fatigue over time.

10. The very substantial change in microstructure produced by the chemistry modifications we made was entirely unexpected and very significant. The change was not merely a slight adjustment to microstructure, but unexpectedly resulted in a fundamentally different and well tolerated microstructure. Fortunately, the new microstructure of the alloy directly addressed the microstructural problems in the conventional MP35N alloy.

The unexpected, surprising, and advantageous microstructure of the alloy recited in claim 1 is a property of the alloy. The Office Action does not refer to this evidence of unexpected results and, thus, Applicants assume that the Office has not considered it. MPEP 2145 ("Consideration of rebuttal evidence and arguments requires Office personnel to weigh the proffered evidence and arguments."). This evidence of an unexpected and surprising change in a fundamental characteristic of the alloy recited in claim 1 relative to conventional MP35N alloy effectively rebuts any *prima facie* obviousness case that the Examiner may have established. See, e.g., *In re Waymouth*, 499 F.2d 1273, 1276 (CCPA 1974) ("In order to show an unexpected result, we do not believe that the lamp must be inoperable over other ranges, but rather that over the claimed critical range, there be a difference in kind, rather than in degree.").

c. **Commercial Success**

Applicants submitted the Myers Declaration to show that (1) small diameter wire produced from the alloy recited in claim 1 has enjoyed very substantial commercial success, and (2) the commercial success is directly attributable to the unexpectedly and substantially improved fatigue resistance of the alloy. In the Office Action, the Examiner does not take the position that the Myers Declaration does not show a substantial increase in sales of wire produced from the alloy recited in the claims. Instead, the Examiner takes the positions addressed below.

i. **Commensurate in Scope**

The Examiner asserts that the Myers Declaration is "not commensurate in scope with the claims" because the declaration is directed to a wire, while the independent claim is "directed toward merely an alloy composition." Objective evidence of

commercial success is not commensurate with the claims if the claims are broader than the scope of the objective evidence. *Joy Technologies, Inc. v. Manbeck*, 751 F.Supp. 225, 229 (D.D.C. 1990), *aff'd*, 959 F.2d 226 (Fed. Cir. 1992). The claims are broader in scope than the objective evidence if a limitation or element recited in the claim is broader than the limitation or element in the objective evidence. *Id.* Here, however, the alloy from which the wire discussed in the Myers Declaration was formed had a composition and microstructure satisfying each and every element and limitation recited in claim 1 of the Subject Application.

Accordingly, the evidence supplied by the Myers Declaration is commensurate in scope with the claims under examination.

ii. Substantiation

The Examiner also asserts that Applicants have not provided factual evidence substantiating the truth of the following statement in the Myers Declaration: "As manufacturers of pacemaker leads and related products have become familiar with the significantly improved fatigue resistance of 35N LT wire, they increasingly prefer the product over other available wire products suitable for their applications." Applicants, however, did submit supporting evidence – they submitted the Myers Declaration itself. See MPEP 716.02(g) ("The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001.") The foregoing statement in the Myers Declaration is based on Mr. Myer's first-hand knowledge of the market for and consumers of conventional MP35N wire and 35N LT wire for use in pacemaker leads and related products. For example, paragraph 5 of Mr. Myer's declaration explains that he is "responsible for business development and all commercial activity within" Fort Wayne Metals (FWM). Further, paragraph 7 states that Mr. Myers is:

thoroughly familiar with the quantities of 35N LT wire FWM has sold and the gross revenues for such sales, and I routinely interact with FWM's customers for the product and request and obtain comments from those customers about their experiences using the product.

Thus, Mr. Myers directly interacted with FWM's customers for 35N LT wire and obtained their first-hand comments regarding the product. Given Mr. Myer's direct and informed knowledge as to why FWM's customers purchased 35N LT wire, his above-quoted observation in declaration paragraph 7 is not merely an opinion, but rather is direct evidence of FWM's customers' preferences and that they "increasingly prefer the product over other available wire products suitable for their applications." MPEP 716.01(c)(III) ("Although factual evidence is preferable to opinion testimony, such testimony is entitled to consideration and some weight so long as the opinion is not on the ultimate legal conclusion at issue.")

Moreover, the sales figures listed in the table and illustrated in the figures of the Myers Declaration are factual evidence confirming Mr. Myer's statement that FWM's customers "increasingly prefer the [35N LT] product over other available wire products suitable for their applications." As noted in the Myers Declaration, FWM filled its first commercial order for 35N LT wire in June of 2003, and in the second half 2003 filled 15 orders for 35N LT wire for a total of about 357,000 linear feet. Filled orders more than quadrupled in 2004, during which FWM shipped over 19 million feet of 35N LT wire. During 2005, the number of orders was 170% of the 2004 figure, and the total length of wire shipped, just over 55 million linear feet, was about 280% of the 2004 length. In 2006, orders increased to 150% and total linear feet shipped advanced to 190% of the prior year's figures. These large increases in sales of 35N LT wire are not the result of like increases over the period in the numbers of surgical implant procedures performed using small diameter MP35N-type wire – instead, the substantial increases undeniably reflect an increased consumer preference for the FWM wire product made from the alloy of the Subject Application.

Accordingly, Applicants have submitted evidence substantiating the truth of the disputed statement in the Myers Declaration.

iii. Nexus

The Examiner asserts that Applicants have not established a nexus between the sales data supplied in the Myers Declaration and the claimed invention. The Myers Declaration, however, states the following:

11. The substantial commercial success that FWM has had with 35N LT wire is directly attributable to its substantially improved fatigue resistance relative to other alloys suitable for use in surgical implant applications. As manufacturers of pacemaker leads and related products have become familiar with the significantly improved fatigue resistance of 35N LT wire, they increasingly prefer the product over other available wire products suitable for their applications. I do not base this conclusion only on the substantial, rapid, and continuing increase in FWM's sales of 35N LT wire and on the fact that 35N LT wire has largely displaced other available biocompatible alloys for use in several surgical implant applications. I also base this conclusion on direct feedback from customers for 35N LT wire for use in certain surgical implant applications – those customers state that they chose FWM's 35N LT wire over wire formed from other available alloys because of the FWM product's superior fatigue resistance.

The evidence provided in this paragraph, which is based on Mr. Myers' direct knowledge of sales of the 35N LT wire product and direct feedback from customers for the wire is compelling – customers of FWM directly related to Mr. Myers that they chose the product based on its "superior fatigue resistance", rather than for other reasons. Such a statement is not opinion, but rather is direct evidence, as expressed to Mr. Myers by the customers themselves, that the customer's orders for 35N LT wire were motivated by the product's fatigue properties. What evidence could be more focused and compelling on the issue of why customers purchased the product?

Accordingly, Applicants have submitted evidence demonstrating a nexus between the sales data supplied in the Myers Declaration and the claimed invention.

Therefore, the established secondary considerations show that the alloy recited in claim 1 would not have been obvious in view of Smith. It follows that rejected claims 2, 4-8, 10, 12, 16-20, 32-34, and 53, which directly or ultimately depend from claim 1, also would not have been obvious over Smith. Accordingly, the Examiner should withdraw his rejection based on Smith.

3. New Claim 54

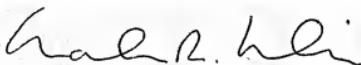
Applicants herein supplement the claim set to include new dependent claim 54, which through dependency on claim 32 is directed to a wire comprising the alloy of any of claims 1, 2, 4-8, 10, and 12-20. Claim 54 is fully supported by and does not add new matter to the Subject Application.

Conclusion:

Applicants have made a diligent effort to fully respond to the Office Action and hereby traverse all rejections presented. Applicants respectfully submit that claims 1, 2, 4-8, 10, 12-20, 32-34, 53, and 54 of the Subject Application are in condition for allowance. Applicants respectfully request issuance of a Notice of Allowance at an early date.

Applicants' present response should not in any way be taken as acquiescence to any of the specific assertions, statements, etc., presented in the Office Action not explicitly addressed herein. Applicants reserve the right to specifically address all such assertions and statements in subsequent responses

Respectfully submitted,



Mark R. Leslie
Registration No. 36,360

Kirkpatrick & Lockhart Preston Gates Ellis LLP
Henry W. Oliver Building
535 Smithfield Street
Pittsburgh, Pennsylvania 15222-2312

Phone: (412) 355-6271